

Liza M. Walsh
WALSH, PIZZI, O'REILLY, FALANGA LLP
One Riverfront Plaza
1037 Raymond Blvd., Suite 600
Newark, NJ 07102
(973) 757-1100

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS LIMITED, ALLERGAN USA, INC., and PIERRE FABRE MEDICAMENT S.A.S.,)))))) Plaintiffs,)))))) v.)))))) WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED and WEST- WARD PHARMACEUTICALS CORP.,)))))) Defendants.))))	
						C.A. No.:
						<i>Electronically Filed</i>

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.), Forest Laboratories Holdings Limited, Allergan USA, Inc. (collectively, "Forest"), and Pierre Fabre Medicament S.A.S. (collectively, with Forest, "Plaintiffs") file this Complaint for patent infringement against Defendants West-Ward Pharmaceuticals International Limited and West-Ward Pharmaceuticals Corp. (collectively, "West-Ward") under 35 U.S.C. §§ 271(e)(2), (a), (b), and (c). This patent action concerns the pharmaceutical drug product Fetzima® and West-Ward's infringement of United States Patent Nos. 8,481,598 ("the '598 patent"), 8,865,937 ("the '937 patent"), and RE43,879 ("the '879 patent"). Plaintiffs hereby allege as follows:

JURISDICTION AND PARTIES

1. Plaintiff Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.) (“Forest Labs”) is a Delaware limited liability company having a place of business at 5 Giralda Farms, Madison, New Jersey 07940.

2. Plaintiff Forest Laboratories Holdings Limited (“Forest Holdings”) is a corporation organized under the laws of the Republic of Ireland having offices at Canon’s Court, 22 Victoria Street, Hamilton HM 12 Bermuda.

3. Plaintiff Allergan USA, Inc. (“Allergan”) is a Delaware corporation having a place of business at 5 Giralda Farms, Madison, New Jersey 07940.

4. Plaintiff Pierre Fabre Medicament S.A.S. (“Pierre Fabre”) is a corporation organized under the laws of France having offices at 45, Place Abel Gance 92100 Boulogne - France.

5. On information and belief, Defendant West-Ward Pharmaceuticals International Limited (“West-Ward Pharma”) is a United Kingdom Corporation, having a principal place of business at 1 New Burlington Place, London, England W1S 2HR and 401 Industrial Way West, Eatontown, New Jersey 07724.

6. On information and belief, Defendant West-Ward Pharmaceuticals Corp. (“West-Ward Corp.”) is a Delaware corporation, having its principal place of business at 401 Industrial Way West, Eatontown, New Jersey 07724.

7. On information and belief, West-Ward Pharma is a generic pharmaceutical company in the business of marketing and developing generic drug products. On information and

belief, West-Ward Pharma directly and through its affiliates markets and sells drug products in the State of New Jersey and throughout the United States.

8. On information and belief, West-Ward Corp. is a generic pharmaceutical company in the business of marketing and developing generic drug products. On information and belief, West-Ward Corp. directly and through its affiliates markets and sells drug products in the State of New Jersey and throughout the United States.

9. On information and belief, West-Ward Corp. is an agent or affiliate of West-Ward Pharma and is acting as an agent of West-Ward Pharma with respect to Abbreviated New Drug Application (“ANDA”) No. 210732.

10. West-Ward “has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at,” upon information and belief, the District of New Jersey and elsewhere. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 759 (Fed. Cir. 2016), *cert. denied*, 2017 WL 69716 (U.S. Jan. 9, 2017). West-Ward’s “ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs.” *Id.* at 760. On information and belief, West-Ward “intends to direct sales of its drugs into [New Jersey], among other places, once it has the requested FDA approval to market them.” *Id.* at 758. Upon information and belief, West-Ward will market its proposed ANDA products the United States, including New Jersey, upon approval of its ANDA.

11. West-Ward has affirmatively availed itself of this Court’s jurisdiction by filing counterclaims in this district, and was previously sued in this district and did not challenge personal jurisdiction. *See, e.g., Janssen Biotech, Inc. et al., v. West-Ward et al.*, 15-cv-5909 (D.N.J. Oct. 15, 2015).

12. For the reasons stated above, this Court has personal jurisdiction over West-Ward.

13. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (c), and § 1400(b) because, on information and belief, West-Ward Pharma is incorporated in the United Kingdom and may be sued in any judicial district in the United States, in which the defendant is subject to the court's personal jurisdiction.

14. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (c), and § 1400(b) because, on information and belief, West-Ward Corp. has a principal place of business in New Jersey and has and will continue to engage in infringing activities in New Jersey.

15. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2). This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

COUNT I FOR PATENT INFRINGEMENT

(Infringement of the '598 Patent Under 35 U.S.C. § 271(e)(2))

16. Plaintiffs reallege and incorporate by reference paragraphs 1-15.

17. The '598 patent, titled "Stable Dosage Forms of Levomilnacipran," was duly and legally issued to inventors Rahul Surana, Murali Divi, and Anil Chhettry by the United States Patent and Trademark Office ("PTO") on July 9, 2013. The '598 patent is assigned to Forest Holdings and expires on March 2, 2031. This expiration date includes a 114-day patent term adjustment granted by the PTO pursuant to 35 U.S.C. § 154(b). A true and correct copy of the '598 patent is attached as Exhibit A. A true and correct copy of the Certificate Adjusting Patent Term is attached as Exhibit B.

18. New Drug Application ("NDA") No. 204168 is directed to the use of Fetzima® for the treatment of major depressive disorder ("MDD"). The FDA approved NDA No. 204168

on July 25, 2013. The '598 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 204168.

19. Plaintiff Forest Holdings is the assignee of the '598 patent. Forest Labs is the NDA holder for extended release capsules containing 20 mg, 40 mg, 80 mg, and 120 mg of the active ingredient levomilnacipran in the United States, which are sold under the brand name Fetzima®. Allergan is a distributor of Fetzima® in the United States.

20. On information and belief, West-Ward filed, or caused to be filed, ANDA No. 210732 with the FDA under 21 U.S.C. § 355(j), seeking approval for the commercial manufacture, use, and sale of levomilnacipran hydrochloride extended release capsules in 20 mg, 40 mg, 80 mg, and 120 mg dosage strengths in the United States before the '598 patent expires ("West-Ward's generic levomilnacipran products").

21. On information and belief, ANDA No. 210732 contains a Paragraph IV certification alleging that all claims of the '598 are invalid and/or not infringed.

22. West-Ward sent, or caused to be sent, to Plaintiffs a letter dated September 20, 2017 ("West-Ward's Notice Letter") notifying Plaintiffs that West-Ward submitted ANDA No. 210732, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). West-Ward's Notice Letter alleges that claims 1-8 of the '598 patent are invalid. West-Ward did not allege noninfringement of claims 1-6.

23. On information and belief, West-Ward seeks approval of at least one indication for West-Ward's generic levomilnacipran products that are claimed in the '598 patent.

24. Under 35 U.S.C. § 271(e)(2)(A), West-Ward infringed one or more claims of the '598 patent in violation of Plaintiffs' patent rights, by submitting an ANDA to the FDA that seeks approval to commercially market—before the '598 patent expires—West-Ward's generic levomilnacipran products, the use of which would directly infringe one or more claims of the '598 patent, literally and/or through the doctrine of equivalents, and the manufacture, use, offer for sale, or sale within the United States, or importation into the United States would contribute to or induce the direct infringement of one or more claims of the '598 patent, by users of West-Ward's generic levomilnacipran products.

25. On information and belief, West-Ward has knowledge of the '598 patent and filed ANDA No. 210732 seeking authorization to commercially manufacture, use, offer for sale, and sell West-Ward's generic levomilnacipran products in the United States. On information and belief, if the FDA approves ANDA No. 210732, physicians, health care providers, and/or patients will use West-Ward's generic levomilnacipran products according to West-Ward's provided instructions and/or label and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '598 patent.

26. On information and belief, West-Ward knows and intends that physicians, health care providers, and/or patients will use West-Ward's generic levomilnacipran products according to West-Ward's provided instructions and/or label, and will therefore induce infringement of one or more claims of the '598 patent with the requisite intent.

27. On information and belief, if the FDA approves ANDA No. 210732, West-Ward will sell or offer to sell its generic levomilnacipran products specifically labeled for use in practicing one or more of the method claims of the '598 patent, wherein West-Ward's generic

levomilnacipran products are a material part of the method claimed, wherein West-Ward knows that physicians will prescribe and patients will use West-Ward's generic levomilnacipran products in practicing one or more of the methods claimed in the '598 patent, and wherein levomilnacipran is not a staple article or commodity of commerce suitable for substantial noninfringing use. West-Ward will thus contribute to the infringement of the '598 patent.

28. Plaintiffs will be substantially and irreparably harmed by West-Ward's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT II FOR PATENT INFRINGEMENT

(Infringement of the '937 Patent Under 35 U.S.C. § 271(e)(2))

29. Plaintiffs reallege and incorporate by reference paragraphs 1-28.

30. The '937 patent, titled "Crystalline Forms of (1S, 2R)-2-(Amino methyl)-N, N-Diethyl-1-Phenyl Cyclopropane Carboxamide," was duly and legally issued to inventors Mahendra G. Dedhiya and Rahul Surana by the PTO on October 21, 2014. The '937 patent is assigned to Forest Holdings and expires on May 23, 2032. This expiration date includes a 562-day patent term adjustment granted by the PTO pursuant to 35 U.S.C. § 154(b). A true and correct copy of the '937 patent is attached as Exhibit C. A true and correct copy of the Certificate Adjusting Patent Term is attached as Exhibit D.

31. NDA No. 204168 is directed to the use of Fetzima® for the treatment of MDD. The FDA approved NDA No. 204168 on July 25, 2013. The '937 patent is listed in the Orange Book for NDA No. 204168.

32. Plaintiff Forest Holdings is the assignee of the '937 patent. Forest Labs is the NDA holder for extended release capsules containing 20 mg, 40 mg, 80 mg, and 120 mg of the

active ingredient levomilnacipran in the United States, which are sold under the brand name Fetzima®. Allergan is a distributor of Fetzima® in the United States.

33. On information and belief, West-Ward filed, or caused to be filed, ANDA No. 210732 with the FDA under 21 U.S.C. § 355(j), seeking approval to commercially manufacture, use, and sell West-Ward's generic levomilnacipran products in the United States before the '937 patent expires.

34. On information and belief, ANDA No. 210732 contains a Paragraph IV certification alleging that all claims of the '937 patent are invalid and/or not infringed.

35. West-Ward sent, or caused to be sent, to Plaintiffs, West-Ward's Notice Letter notifying Plaintiffs that West-Ward submitted ANDA No. 210732, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). West-Ward's Notice Letter alleges that claims 1-13 of the '937 patent are invalid. West-Ward did not allege noninfringement of claim 1 of the '937 patent.

36. On information and belief, West-Ward seeks approval for at least one indication of West-Ward's generic levomilnacipran products that are claimed in the '937 patent.

37. Under 35 U.S.C. § 271(e)(2)(A), West-Ward infringed one or more claims of the '937 patent in violation of Plaintiffs' patent rights, by submitting an ANDA to the FDA that seeks approval to commercially market—before the '937 patent expires—West-Ward's generic levomilnacipran products. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States of West-Ward's generic levomilnacipran products would

directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '937 patent.

38. Plaintiffs will be substantially and irreparably harmed by West-Ward's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT III FOR PATENT INFRINGEMENT
(Infringement of the '879 Patent Under 35 U.S.C. § 271(e)(2))

39. Plaintiffs reallege and incorporate by reference paragraphs 1-38.

40. The '879 patent, titled "Use of the Dextrogyral Enantiomer of Milnacipran for the Preparation of a Drug," was duly and legally reissued to inventors Jean Deregnaucourt and Richard Grosse by the PTO on December 25, 2012. The '879 patent is assigned to Pierre Fabre and expires on June 3, 2023. A true and correct copy of the '879 patent is attached as Exhibit E. An application for Patent Term Extension pursuant to 35 U.S.C. § 156 is currently pending.

41. NDA No. 204168 is directed to the use of Fetzima® for the treatment of MDD. The FDA approved NDA No. 204168 on July 25, 2013. The '879 patent is listed in the Orange Book for NDA No. 204168.

42. Plaintiff Pierre Fabre is the assignee of the '879 patent and Forest Holdings is the exclusive licensee of the '879 patent. Forest Labs is the NDA holder for extended-release capsules containing 20 mg, 40 mg, 80 mg, and 120 mg of the active ingredient levomilnacipran in the United States, which are sold under the brand name Fetzima®. Allergan is a distributor of Fetzima® in the United States.

43. On information and belief, West-Ward filed, or caused to be filed, ANDA No. 210732 with the FDA under 21 U.S.C. § 355(j), seeking approval to commercially manufacture, use, and sell West-Ward's generic levomilnacipran products in the United States before the '879 patent expires.

44. On information and belief, ANDA No. 210732 contains a Paragraph IV certification alleging that all claims of the '879 patent are invalid and/or not infringed.

45. West-Ward sent, or caused to be sent, to Plaintiffs, West-Ward's Notice Letter notifying Plaintiffs that West-Ward submitted ANDA No. 210732, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). West-Ward's Notice Letter alleges that all claims of the '879 patent are invalid. West-Ward did not allege noninfringement of claims 1-9 and 23-25 of the '879 patent.

46. On information and belief, West-Ward seeks approval for at least one indication of West-Ward's generic levomilnacipran products that are claimed in the '879 patent.

47. Under 35 U.S.C. § 271(e)(2)(A), West-Ward infringed one or more claims of the '879 patent in violation of Plaintiffs' patent rights, by submitting an ANDA to the FDA seeking approval to commercially market—before the '879 patent expires—West-Ward's generic levomilnacipran products, the use of which would directly infringe one or more claims of the '879 patent, literally and/or through the doctrine of equivalents, and the manufacture, use, offer for sale, or sale within the United States, or importation into the United States would contribute to or induce the direct infringement of one or more claims of the '879 patent, by users of West-Ward's generic levomilnacipran products.

48. On information and belief, West-Ward has knowledge of the '879 patent and filed ANDA No. 210732 seeking authorization to commercially manufacture, use, offer for sale, and sell West-Ward's generic levomilnacipran products in the United States. On information and belief, if the FDA approves ANDA No. 210732, physicians, health care providers, and/or patients will use West-Ward's generic levomilnacipran products according to West-Ward's provided instructions and/or label and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '879 patent.

49. On information and belief, West-Ward knows and intends that physicians, health care providers, and/or patients will use West-Ward's generic levomilnacipran products according to West-Ward's provided instructions and/or label, and will therefore induce infringement of one or more claims of the '879 patent with the requisite intent.

50. On information and belief, if the FDA approves ANDA No. 210732, West-Ward will sell or offer to sell its generic levomilnacipran products specifically labeled for use in practicing one or more of the method claims of the '879 patent, wherein West-Ward's generic levomilnacipran products are a material part of the method claimed, wherein West-Ward knows that physicians will prescribe and patients will use West-Ward's generic levomilnacipran products in practicing one or more of the methods claimed in the '879 patent, and wherein levomilnacipran is not a staple article or commodity of commerce suitable for substantial noninfringing use. West-Ward will thus contribute to the infringement of the '879 patent.

51. Plaintiffs will be substantially and irreparably harmed by West-Ward's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT IV FOR DECLARATORY JUDGMENT

(Declaratory Judgment of Patent Infringement of the '598 Patent Under
35 U.S.C. § 271 (b), and/or (c))

52. Plaintiffs reallege and incorporate by reference paragraphs 1-51.

53. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(b)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

54. On information and belief, West-Ward, upon the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of West-Ward's generic levomilnacipran products so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '598 patent under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiffs' patent rights.

55. On information and belief, West-Ward has knowledge of the '598 patent and has filed ANDA No. 210732 seeking authorization to commercially manufacture, use, offer for sale, and sell West-Ward's generic levomilnacipran products in the United States. On information and belief, if the FDA approves ANDA No. 210732, physicians, health care providers, and/or patients will use West-Ward's generic levomilnacipran products according to West-Ward's provided instructions and/or label and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '598 patent in violation of Plaintiffs' patent rights.

56. On information and belief, West-Ward knows and intends that physicians, health care providers, and/or patients will use West-Ward's generic levomilnacipran products according to West-Ward's provided instructions in the '598 patent and/or label with the requisite intent under 35 U.S.C. § 271(b).

57. On information and belief, if the FDA approves ANDA No. 210732, West-Ward will sell or offer to sell its generic levomilnacipran products specifically labeled for use in practicing one or more claims of the '598 patent, wherein West-Ward's generic levomilnacipran products are a material part of the invention claimed in the '598 patent, wherein West-Ward knows that physicians will prescribe and patients will use West-Ward's generic levomilnacipran products for practicing one or more claims in the '598 patent, and wherein levomilnacipran is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, West-Ward will thus contribute to the infringement of the '598 patent under 35 U.S.C. § 271(c).

58. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and West-Ward as to liability for infringement of the '598 patent claims. West-Ward's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from West-Ward's threatened imminent actions.

COUNT V FOR DECLARATORY JUDGMENT

(Declaratory Judgment of Patent Infringement of the '937 Patent Under
35 U.S.C. § 271 (a))

59. Plaintiffs reallege and incorporate by reference paragraphs 1-58.

60. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

61. On information and belief, West-Ward, upon the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of West-Ward's generic levomilnacipran products so labeled, if approved by the FDA, will infringe one or more claims of the '937 patent under 35 U.S.C. § 271(a) in violation of Plaintiffs' patent rights.

62. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and West-Ward as to liability for infringement of the '937 patent claims. West-Ward's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from West-Ward's threatened imminent actions.

COUNT VI FOR DECLARATORY JUDGMENT

(Declaratory Judgment of Patent Infringement of the '879 Patent Under
35 U.S.C. § 271 (b), and/or (c))

63. Plaintiffs reallege and incorporate by reference paragraphs 1-62.

64. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(b)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

65. On information and belief, West-Ward, upon the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of West-Ward's generic levomilnacipran products so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '879 patent, under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiffs' patent rights.

66. On information and belief, West-Ward has knowledge of the '879 patent and filed ANDA No. 210732 seeking authorization to commercially manufacture, use, offer for sale, and sell West-Ward's generic levomilnacipran products in the United States. On information and belief, if the FDA approves ANDA No. 210732, physicians, health care providers, and/or patients will use West-Ward's generic levomilnacipran products according to West-Ward's provided instructions and/or label and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '879 patent, in violation of Plaintiffs' patent rights.

67. On information and belief, West-Ward knows and intends that physicians, health care providers, and/or patients will use West-Ward's generic levomilnacipran products according to West-Ward's provided instructions in the '879 patent and/or label with the requisite intent under 35 U.S.C. § 271(b).

68. On information and belief, if the FDA approves ANDA No. 210732, West-Ward will sell or offer to sell its generic levomilnacipran products specifically labeled for use in practicing one or more claims of the '879 patent, wherein West-Ward's generic levomilnacipran products are a material part of the invention claimed in the '879 patent, wherein West-Ward knows that physicians will prescribe and patients will use West-Ward's generic levomilnacipran products for practicing one or more claims in the '879 patent, and wherein levomilnacipran is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, West-Ward will thus contribute to the infringement of the '879 patent under 35 U.S.C. § 271(c).

69. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and West-Ward as to liability for infringement of the '879 patent claims. West-Ward's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from West-Ward's threatened imminent actions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor as follows:

- a) declare that, under 35 U.S.C. § 271(e)(2)(A), West-Ward infringed United States Patent Nos. 8,481,598, 8,865,937, and RE43,879 by submitting ANDA No. 210732 to the FDA for approval to commercially manufacture, use, offer for sale, sell, or import into the United States West-Ward's generic levomilnacipran products before the said patents expire;

- b) declare that West-Ward's commercial manufacture, use or sale, or offer for sale in, or importation into the United States of West-Ward's generic levomilnacipran products before United States Patent Nos. 8,481,598 and RE43,879 expire, would constitute infringement of one or more claims of said patents under 35 U.S.C. § 271(b) and/or (c);
- c) declare that West-Ward's commercial manufacture, use or sale, or offer for sale in, or importation into the United States of West-Ward's generic levomilnacipran products before United States Patent No. 8,865,937 expire, would constitute infringement of one or more claims of said patents under 35 U.S.C. § 271(a);
- d) declare that United States Patent Nos. 8,481,598, 8,865,937, and RE43,879 are valid;
- e) order that the effective date of any FDA approval for West-Ward's generic levomilnacipran products shall be no earlier than the expiration date of United States Patent Nos. 8,481,598, 8,865,937, and RE43,879, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(A);
- f) enjoin West-Ward, and all persons acting in concert with West-Ward, from seeking, obtaining, or maintaining final approval for ANDA No. 210732 until United States Patent Nos. 8,481,598, 8,865,937, and RE43,879 expire, including any exclusivities or extensions to which Plaintiffs are or become entitled;
- g) enjoin West-Ward, and all persons acting in concert with West-Ward, from commercially manufacturing, using, offering for sale, or selling West-Ward's generic levomilnacipran products within the United States, or importing West-Ward's generic levomilnacipran products into the United States, until United States Patent Nos. 8,481,598, 8,865,937, and RE43,879 expire, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(B);
- h) enjoin West-Ward, and all persons acting in concert with West-Ward, from commercially manufacturing, using, offering for sale, or selling West-Ward's generic levomilnacipran products within the United States, or importing West-Ward's generic levomilnacipran products into the United States, until United States Patent Nos. 8,481,598, 8,865,937, and RE43,879 expire, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 283;
- i) declare this to be an exceptional case and award Plaintiffs their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4); and

j) grant Plaintiffs such further and additional relief that this Court deems just and proper.

Respectfully submitted,

Dated: October 31, 2017

By: s/Liza M. Walsh
Liza M. Walsh
WALSH PIZZI O'REILLY FALANGA LLP
One Riverfront Plaza
1037 Raymond Blvd., Suite 600
Newark, NJ 07102
(973) 757-1100

Of Counsel (pro hac vice forthcoming):

Howard W. Levine
Sanya Sukduang
Courtney B. Casp
Danielle A. Duszczyszyn
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

Attorneys for Plaintiffs

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 401

I hereby certify that, to the best of my knowledge, the matter in controversy is related to the matter captioned *Forest Laboratories, LLC et al. v. MSN Laboratories Private Limited et al.*, Civ. A. No. 17-10140 (ES)(SCM) because it involves the same Plaintiffs, the same patents, and in both cases the defendants are seeking approval to market generic versions of the same pharmaceutical product.

I further certify that the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: October 31, 2017

By: s/Liza M. Walsh
Liza M. Walsh
WALSH PIZZI O'REILLY FALANGA LLP
One Riverfront Plaza
1037 Raymond Blvd., Suite 600
Newark, NJ 07102
(973) 757-1100

Of Counsel (pro hac vice forthcoming):

Howard W. Levine
Sanya Sukduang
Courtney B. Casp
Danielle A. Duszczyszyn
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

Attorneys for Plaintiffs

RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, inter alia, injunctive relief.

Dated: October 31, 2017

By: s/Liza M. Walsh
Liza M. Walsh
WALSH PIZZI O'REILLY FALANGA LLP
One Riverfront Plaza
1037 Raymond Blvd., Suite 600
Newark, NJ 07102
(973) 757-1100

Of Counsel (pro hac vice forthcoming):

Howard W. Levine
Sanya Sukduang
Courtney B. Casp
Danielle A. Duszczyszyn
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

Attorneys for Plaintiffs